DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

August 29, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref: KAN 2001-031

Mr. Richard B. Johnson, CEO
Hammer Medical Supply
1801 2nd Avenue
Des Moines, Iowa 50314

Dear Mr. Johnson:

During an inspection of your medical oxygen transfilling operations at the above address by an investigator of this office on July 23-27, 2001, significant deviations from Current Good Manufacturing Practice regulations (CGMP), Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211) were observed. Drugs products that are not manufactured in compliance with CGMP regulations are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Deviations from CGMP regulations noted during the inspection included, but were not limited to the following:

Failure to establish and operate an effective quality control unit in conformity with requirements of 21 CFR 211.22. There are no written procedures concerning individual responsibility for quality control operations. Drug manufacturing records (medical oxygen transfilling records) contained numerous errors and omissions, although they had undergone quality control review. Written standard operating procedures covering drug manufacture were inaccurate, incomplete, and contained no documentation of origin, review, or approval.

Failure to follow written production and process control procedures as required by 21 CFR 211.100. A significant example is the failure to conduct identity and purity testing of some transfilled medical oxygen as required by SOPs.

Failure to establish and implement an effective employee CGMP training program as required by 21 CFR 211.25. Employee training records contain no reference to CGMP training, there are no CGMP training SOPs in place, and at least one employee denied knowledge of CGMP regulations.

The above-described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of warning letters issued to drug manufacturers so that inspectional information can be taken into account in the awarding of contracts.

You should take prompt action to correct all violations of the Act. Failure to do so could result in regulatory actions such as seizure, and/or injunction without further notice.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, P.O. Box 15905, Lenexa, Kansas 66285-5905, to the attention of Noel G. Ferguson, Compliance Officer. Any questions regarding this letter may be directed to Mr. Ferguson at (913) 752-2102.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District